#### REMARKS

A STATEMENT OF STATUS OF CLAIMS AND SUPPORT FOR CLAIM CHANGES 37 CFR 1.173(c) is ATTACHMENT 1 herewith.

The Office Action in Paragraph Nos. 1, 2, 5 and 6 set forth a number of objections and rejections which are based on the Reissue Declaration not setting forth the foreign priority data. Paragraph No. 5 notes that a Supplemental Reissue Declaration "must be received before this reissue application can be allowed". A Supplemental Reissue Declaration will be filed shortly after the filing of this Amendment. This will provide time for applicants to consider the amendments presented herein which include correction of errors.

The Office Action, Paragraph No. 3, requires the filing of an offer to surrender the original patent or, if the original patent is lost or inaccessible, an affidavit or declaration to that effect. A REISSUE APPLICATION BY THE ASSIGNEE, OFFER TO SURRENDER PATENT (37 CFR 1.178(a)) is ATTACHMENT 2 herewith.

The Office Action, Paragraph Nos. 7 and 8, base a rejection on an error in claim 36. The Examiner is thanked for pointing out the error and for suggesting the correction. The present amendment to claim 36 includes correction of the noted error.

The Office Action, Paragraph Nos. 9 and 10, reject claims 1-15, 27-29 and 39-43 under 35 USC 102(e) over the Khanna et al USP 5,935,990.

The Office Action, Paragraph Nos. 11 and 12, reject claims 1-24, 27-30 and 39-43 under 35 USC 103(a) over the same USP 5,935,990.

Both of the above rejections are based upon USP 5,935,990 being a reference as of December 10, 1996 under 35 USC 102(e). The present reissue application is for reissue of USP 5,908,858 which issued on application SN 08/824,775 filed March 26, 1997. In SN 08/824,775 the April 5, 1996 priority date of JP 8-083562 was claimed. A certified copy of JP 8-083562 was timely filed during the prosecution of SN 08/824,775. In the present reissue application, a foreign priority claim for the priority of JP 8-083562 filed April 5, 1996 was filed November 27, 2000.

In the Office Action, Paragraph No. 13, it is stated that applicant cannot rely upon on the present foreign priority papers to overcome the rejections under 35 USC 102(e) and 35 USC 103 "because a translation of said papers has not been made of record in accordance with 37 CFR 1.55...nor has Applicant complied with the requirements of 37 CFR 1.63(C)". An English-language translation of JP 8-083562 together with a STATEMENT OF ACCURACY OF TRANSLATION OF PRIORITY DOCUMENT (37 CFR 1.55(a)) is enclosed

herewith and made a part hereof.

The reissue application claims which were rejected under 35 US 102(e) and 35 USC 103 have been amended so that each amended claim is fully supported by the disclosure in JP 8-083562. An EXPLANATION OF SUPPORT IN PRIORITY APPLICATION JP 8-083562 FOR REISSUE APPLICATION CLAIMS is ATTACHMENT 3 herewith.

It is respectfully submitted that the filing of the Supplemental Reissue Declaration shortly and the English-language translation of the priority document together with the present amendment and Attachment 3 establishes that applicant is entitled to the benefit of the April 5, 1996 date under 35 USC 119. Since this date is earlier than the 35 USC 102(e) date of the Khanna USP 5,935,990, said Khanna USP 5,935,990 is not a reference against the present reissue application.

It is considered that there is an interference situation between (i) claims in USP 5,908,858 (and in the claims in this application for reissue application of USP 5,908,858) and (ii) claims in the Khanna USP 5,935,990.

There is no rejection of claims 31-38 under 35 USC 102 and/or 35 USC 103. Accordingly, amended claims 31-33 and new claims 53-61 which depend from claim 31; and amended claims 35-37

and new claims 62-70 which depend from claim 35, are allowable.

Reconsideration of the rejections is solicited.

Please apply the enclosed check in the amount of \$664.00 as the additional filing fee required by the present amendment (see the enclosed PTO Form PTO/SB/56 entitled REISSUE APPLICATION FEE TRANSMITTAL FORM).

Respectfully submitted,

FERBERT GOODMAN

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HG/fs

### ATTACHMENT 1

Attorney Docket No. 970113R/HG

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First named

Applicant : Kimura

Serial No. : 09/678,218

Filed : September 29, 2000

Art Unit : 1626

Examiner : L. Stockton

# STATEMENT OF STATUS OF CLAIMS AND SUPPORT FOR CLAIM CHANGES 37 CFR 1.173(c)

Assistant Commissioner for Patents

SIR:

Except as noted below, the claims which are being amended by the Amendment of even date are amended so that each such amended claim is fully supported by the priority application, JP 08-083562.

Claims 31-33 (and new claims 53-61 which depend from claim 31); and claims 35-37 (and new claims 62-70 which depend from claim 35) have not been amended for the purposes noted in the preceding sentence. A claim for the priority of JP 08-083562 is not being made for the claims identified in this paragraph.

In the following which provides "...an explanation of the support in the disclosure of the patent for the changes made to the claims", it is noted that all of the amendments involve deletion of subject matter from the patent claims and/or a narrowing of the range(s) of carbon atoms specified in the patent claims. It is submitted that the patent claims are "disclosure in the patent" for the changes which are made. All of the changes to the claims are also supported in other parts of the specification. In the following explanation, subject matter which is deleted is not always discussed.

Claim 1 (pending): The amended definition of  $R^1$  is supported by the disclosure in column 7, line 12. The  $R^3$  amendment (i) of the alkyl group is supported by the disclosure in column 10, line 20; and (ii) of the alkoxy group and of the alkylthio group by the disclosure in column 10, line 7 and column 7, lines 26-28. The  $R^4$  alkoxy and alkylthio group amendments are supported by the disclosure in column 7, lines 26-28 and the disclosure in column 11, lines 52-60 and line 67 which also support the amendments to the definitions of "substituents  $\alpha$ " and "substituents  $\beta$ ".

Claim 2 (cancelled).

Claim 3 (cancelled).

Claim 4 (cancelled).

Claim 5 (cancelled).

Claim 6 (pending): There is a deletion of subject matter.

Claim 7 (pending): There is a change in dependency.

Claim 8 (pending): There is a change in dependency and the deletion of subject matter.

Claim 9 (pending): There is a change in dependency.

Claim 10 (pending): There is a change in dependency.

Claim 11 (pending): There is a change in dependency. The amendments to the definition of  $R^4$  parallel the amendments to the definition of  $R^4$  in claim 1 with the further feature of the unsubstituted or substituted alkyl group having  $C_1$ - $C_4$  carbon atoms which is supported in column 11, lines 5 and 6.

Claim 12 (pending): There is a change in dependency. The amendments to the definition of  $R^4$  parallel the amendments to the definition of  $R^4$  in claim 1 with the further feature of the

unsubstituted or substituted alkyl group having  $C_1$ - $C_4$  carbon atoms which is supported in column 11, lines 5 and 6.

Claim 13 (pending): With the exception of the deleted subject matter, the amendments are in the definition of  $R^4$  which parallel the amendments in claim 1 with the further feature of the unsubstituted or substituted alkyl group having  $C_1$ - $C_4$  carbon atoms which is supported in column 11, lines 5 and 6.

Claim 14 (pending): There is a change in dependency and there is a deletion of subject matter. Additionally, the compound is limited to a compound of the formula (II).

Claim 15 (pending): There is a change in dependency and deleiton of subject matter. The R<sup>3</sup> amendment is supported by the disclosure in column 10, lines 13, 21 and 23. Additionally, the compound is limited to a compound of the formula (II).

Claim 16 (pending): Not amended.

Claim 17 (pending): Not amended.

Claim 18 (pending): Not amended.

Claim 19 (pending): Not amended.

Claim 20 (pending): Not amended.

Claim 21 (pending): Not amended.

Claim 22 (pending): Not amended.

Claim 23 (pending): Not amended.

Claim 24 (pending): Not amended.

Claim 25 (cancelled).

Claim 26 (cancelled).

Claim 27 (pending): The amendment corrects an obvious error which is supported by column 4, lines 8-10. Not otherwise amended (except to the extent that claim 1 from which it depends is amended).

Claim 28 (pending): Limited to the compounds of the formula (II). The definitions of the  $R-R^4$  groups parallel the definitions in claim 13 and the support is the same as set forth hereinbefore for claims 1 and 13.

Claim 29 (pending): Limited to the compounds of the formula (II). The definitions of the  $R-R^4$  groups parallel the definitions in claim 15 and the support is the same as set forth hereinbefore for claims 1 and 15.

Claim 30 (cancelled): Claim 30 recited a Markush of 11 named compounds. New Claims 44-52 replace cancelled claim 30 with each of claims 44-52 being directed to a respective compound of the first nine compounds named in claim 30.

Claim 31 (pending): The amendment rewrites claim 31 in independent form by including all the features of reissue application claim 1 as filed (which included an amendment to the patent claim 1).

Claim 32 (pending): Limited to the compounds of the formula (II). Support for the specified compounds is the same as for amended claim 28.

Claim 33 (pending): Limited to the compounds of the formula (II). Support for the specified compounds is the same as for amended claim 29.

Claim 34 (cancelled): Claim 34 recited a Markush of 11 named compounds. Claims 53-61 replace cancelled claim 34 with each of

claims 53-61 being directed to a respective compound of the first nine compounds of claim 34.

Claim 35 (pending): The amendment rewrites claim 35 in independent form by including all the features of reissue application claim 1 as filed (which included an amendment to the patent claim 1).

Claim 36 (pending): Limited to the compounds of the formula (II). Support for the specified compounds is the same as for amended claim 28. Additionally, claim 36 corrects the error pointed out by the Examiner in the Office Action by replacing the first " $\mathbb{R}^2$ " with  $-\mathbb{R}^1$ --.

Claim 37 (pending): Limited to the compounds of the formula (II). Support for the specified compounds is the same as

amended claim 29.

Claim 38 (cancelled): Claim 38 recited a Markush of 11 named compounds. Claims 62-70 replace cancelled claim 38 with each of claims 62-70 being directed to a respective compound of the first nine compounds named in claim 38.

Claim 39 (pending): Not amended (except to the extent that claim 1 from which it depends is amended).

Claim 40 (pending): Limited to the compounds of the formula (II). The definition of the  $R-R^4$  groups parallel the definitions in claim 13 and the support therefor is the same as set forth hereinbefore for claims 1 and 13.

Claim 41 (pending): Limited to the compounds of the formula (II). The definition of the  $R-R^4$  groups parallel the definitions in claim 15 and the support therefor is the same as set forth hereinbefore for claims 1 and 15.

Claim 42 (cancelled): Claim 42 recited a Markush of 11 named compounds. Claims 71-79 replace cancelled claim 42 with each of claims 71-79 being directed to a respective compound of the first nine compounds named in claim 42.

Claim 43 (pending): Original claim 43 depended from claim 8 which defines the  $R^2$  group. The present amendment changes the dependency and inserts the reference to  $R^2$ . The amendment to the number of substituent groups is supported by column 7, line 17.

Claims 44-52 (pending) (new): Claims 44-52 replace cancelled claim 30. Claim 44 is directed to the first named compound in

claim 30. Claim 45 is directed to the second named compound.

Claim 46 is directed to the third named compound. Claim 47 is directed to the fourth named compound. Claim 48 is directed to the fifth named compound. Claim 49 is directed to the sixth named compound. Claim 50 is directed to the seventh named compound. Claim 51 is directed to the eighth named compound. Claim 51 is directed to the eighth named compound. Claim 52 is directed to the ninth named compound. The tenth and eleventh named compounds in patent claim 30 were deleted in reissue application claim 30. Claims 44-52 are supported by the disclosure of each of the named compounds in cancelled claim 30 and in one of columns 26, 27 or 28.

Claims 53-61 (pending) (new): Claims 53-61 replace Markush claim 34. The relationship of the respective claims 53-61 to claim 34 and support in the patent for each of these claims is the same as set forth for claims 44-52 except for the different dependency.

Claims 62-70 (pending) (new): Claims 62-70 replace Markush claim 38. The relationship of the respective claims 62-70 to claim 38 and support in the patent for each of these claims is the same as set forth for claims 44-52 except for the different dependency.

Claims 71-79 (pending) (new): These claims replace Markush claim 42. The relationship of the respective claims 71-79 to claim 42 and support in the patent for each of these claims is the same as set forth for claims 44-52 except for the different dependency.

Respectfully submitted,

HERBERT GOODMAN Reg. No. 17,081

Date: September 19, 2001

## ATTACHMENT 2

Attorney Docket No. 970113R/HG

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First named

Applicant : KIMURA

Serial No. : 09/678,218

Filed : September 29, 2000

Art Unit : 1626

Examiner : L. Stockton

# REISSUE APPLICATION BY THE ASSIGNEE, OFFER TO SURRENDER PATENT (37 CFR 1.178(a))

Assistant Commissioner for Patents

SIR:

The above-identified application is an application for reissue of USP 5,908,858, which issued June 1, 1999.

The patentees are Tomio KIMURA, Yasuo NOGUCHI, Akira NAKAO, Keisuke SUZUKI, Shigeru USHIYAMA, Akihiro KAWARA and Masaaki MIYAMOTO.

The patent title is "1,2-DIPHENYLPYRROLE DERIVATIVES, THEIR PREPARATION AND THEIR THERAPEUTIC USES".

Sankyo Company, Limited is the assignee of the entire interest in the original patent.

A copy of the STATEMENT UNDER 37 CFR 3.73(b) which was filed together with the present reissue application is attached.

I offer to surrender the original patent.

I am authorized to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this declaration is directed.

SANKYO COMPANY, LIMITED

Herbert Goodman

Attorney, Registration No. 17,081

Date: September 19, 2001

# OWNERSHIP AND ASSIGNMENT

PTO/S8/96 (5-95)
Approved for use through 09/30/2000. OMB 0551-0031
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STATEMENT UNDER 37 CFR 3.73(b)	
KASPINSTREPATENT OWNER. SANKYO COMPANY, LIMITED	
**************************************	
1,2-DIPHENYLPYRROLE DERIVATIVES, THEIR PREPARATION AN	D
Entitled: THEIR THERAPEUTIC USES	
SANKYO COMPANY, LIMITED a Corporation	
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)	
states that it is:	
1.  the assignee of the entire right, title, and interest; or	
2. an assignee of an undivided part interest	
in the patent application/patent identified above by virtue of either:	_
A. [K.] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the Patent and Trademark Office at Red[870]. Frame 0.107, or for which a copy thereof is attached.	
OR	
B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below	<b>V</b> .
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[ ] Additional documents in the chain of title are listed on a supplemental sheet.	
[ ] Copies of assignments or other documents in the chain of title are attached.  [NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document)  must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the PTO. See MPEP 302-302.8]	
The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.	
12 / 10/10/10	
September 29, 2000 Signature	٠.
Herbert Goodman	
Typed or printed name	
Attorney, Reg. No. 17,081	
Title	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patient and Tradement Office, Washington, DC on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patient and Tradement Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patients, Washington, DC 20231.



## ATTACHMENT 3

Attorney Docket No. 970113R/HG

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First named

Applicant : KIMURA

Serial No. : 09/678,218

Filed : September 29, 2000

Art Unit : 1626

Examiner : L. Stockton

## EXPLANATION OF SUPPORT IN PRIORITY APPLICATION JP 8-083562 FOR REISSUE APPLICATION CLAIMS

Assistant Commissioner for Patents

## SIR:

All references herein to page numbers are to pages in the English-language translation of the priority application

JP 8-083562 which is being filed on the same date as this paper.

All references to claims in the priority application JP 8-083562 are to claims in said English-language translation and will be preceded by "JP". All references to claims in the present reissue application are preceded by "RE".

**RE Claim 1** is supported by the disclosure of the invention starting in the middle of page 7 and continuing through the end of page 8. The definition of the compound on page 7, line 13 through page 8, line 16 (which is the same as JP Claim 1 on

pages 1 and 2) supports RE Claim 1 with the exception that RE Claim 1 specifies alkyl groups, alkoxy groups, alkylthio groups and the alkyl portion of aralkyl groups, in terms of the number of carbon atoms in the alkyl moiety, whereas the JP Claim 1 and page 7-8 disclosure refers to "lower alkyl". Because the reissue application does not use the term "lower alkyl", the number of carbon atoms in the alkyl group or alkyl moiety of the group specified in the definitions of R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup> is identified by a carbon atom range. Further support is discussed below.

The R definition as hydrogen is inherent in the structural formula (I) and formula (II) disclosed on page 7 (and also in JP Claim 1 on page 1) wherein the phenyl ring having the  $SO_2R^1$  substituent does not have any other substituent.

 $R^1$  "methyl or amino group" is disclosed on page 8, line 17.

The  $R^2$ ,  $C_1-C_4$  alkyls are disclosed on page 9, lines 6-29.

The  $R^3$ ,  $C_1-C_4$  alkyls are disclosed on page 10, lines 5-23.

The  $R^4$ ,  $C_1$ - $C_6$  alkyl group is disclosed on page 11, line 2, and the alkyl moiety or alkyl groups which are possible substituents in the  $R^4$  definition, are  $C_1$ - $C_4$  alkyls as disclosed on page 11, line 4 to page 12, line 2. The  $R^4$  definition of the cycloalkyl group as having 3 to 7 carbon atoms is disclosed on

page 11, lines 6 and 7. The R<sup>4</sup> aryl group definition having 6-10 carbon atoms is disclosed on page 11, lines 7-8.

The "substituents  $\alpha$ " and "substituents  $\beta$ " which are included in the  $R^2$  definition and in the  $R^4$  definition are supported by the disclosures identified in the discussion hereinbefore of  $R^2$  and  $R^4$  and particularly page 8, lines 11-12 for substituents  $\alpha$  and lines 13-16 for substituents  $\beta$  (with the number of carbon atoms in the alkyl moieties being disclosed in the places identified hereinabove for the  $R^2$  and  $R^4$  substituents).

RE Claim 6 is supported by JP Claim 3 on page 2.

**RE Claim 7** is supported by JP Claim 4 on page 2 with the number of carbon atoms in the specified alkyl moieties being supported by the same disclosure identified in the definitions of  $\mathbb{R}^2$  and  $\mathbb{R}^4$  of RE Claim 1.

**RE Claim 8** is supported by JP Claim 5 on page 2 with the number of carbon atoms in the specified alkyl moieties being supported by the same disclosure identified in the definitions of  $\mathbb{R}^2$  and  $\mathbb{R}^4$  of RE Claim 1.

RE Claim 9 is supported by JP Claim 7 and disclosure on
page 9, line 30 through page 10, line 12.

<u>**RE Claim 10**</u> is supported by JP Claim 8 when considering the identified disclosure supporting the  $R^3$  definition in RE Claim 1 relative to the number of carbon atoms in the alkyl moieties.

**RE Claims 11 and 12** are supported by the disclosure of JP Claims 9 and 10 (pages 3 and 4) and by the disclosure discussed hereinbefore as supporting the definitions of  $\mathbb{R}^4$  in RE Claim 1.

RE Claims 13, 14 and 15 are directed to combinations of the preferred  $R^2$ ,  $R^3$  and  $R^4$  definitions in JP Claims 7-12 and are supported by the identification of the disclosures discussed hereinbefore supporting said substituents in RE Claim 1.

RE Claim 16 is supported by the disclosure on page 4,
line 23 and on page 24, line 4.

RE Claim 17 is supported by the disclosure on page 4,
line 26 and on page 24, line 8.

RE Claim 18 is supported by the disclosure on page 4,
line 30 and on page 24, line 11.

RE Claim 19 is supported by the disclosure on page 4, line 31 and on page 24, line 12. RE Claim 20 is supported by the disclosure on page 4, line 32 and on page 24, line 13.

RE Claim 21 is supported by the disclosure on page 5, line 1
and on page 24, line 14.

RE Claim 22 is supported by the disclosure on page 5, line 2
and on page 24, line 15.

RE Claim 23 is supported by the disclosure on page 5, line 4
and on page 24, line 17.

**RE Claim 24** is supported by the disclosure on page 16, compound No. 94.

RE Claim 27 is supported by the disclosure on page 5, lines 16-19 (JP Claims 14 and 15); page 43, lines 4-24 and page 100, line 31 through the end of page 103, and by the disclosure identified as supporting the definitions of the compounds in RE Claim 1.

RE Claims 28 and 29 depend from RE Claim 27 and are supported by the same disclosure that supports RE Claim 27. Additionally, the combination of preferred features specified in these claims in terms of the formula (II),  $R^2$ ,  $R^3$  and  $R^4$  are supported by the definitions in JP Claims 7-12 and are supported

by the identification of the disclosure supporting said substituents in RE Claim 1.

RE Claims 31-33 and 35-37: no claim for priority is made for these claims.

RE Claim 39 is supported by the disclosure on page 5, lines 8-10 (JP Claim 12); page 43, lines 4-24, and page 99, line 10 to page 100, line 30, and by the disclosure identified as supporting the definitions of the compounds in RE Claim 1.

RE Claims 40 and 41 depend from RE Claim 39 and are supported by the same disclosure that supports RE Claim 39. Additionally, the combination of preferred features specified in these claims in terms of the formula (II), R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are supported by the definitions in JP Claims 7-12 and are supported by the identification of the disclosure supporting said substituents in RE Claim 1.

**RE Claim 43** is supported by the disclosure on page 3, lines 8-10 (JP Claim 6) and the exemplification on page 9, lines 4-29.

RE Claims 44-52 which depend from RE Claim 27 are supported by the support identified hereinbefore for RE Claim 27 in terms of the method; and by the identification of support in the

priority document for the respective compounds which are respectively the same as the compounds in RE Claims 16-24.

RE Claims 53-61 which depend from RE Claim 31 are supported by the support identified hereinbefore for RE Claim 31 in terms of the method; and by the identification of support in the priority document for the respective compounds which are respectively the same as the compounds in RE Claims 16-24.

RE Claims 62-70 which depend from RE Claim 35 are supported by the support identified hereinbefore for RE Claim 35 in terms of the method; and by the identification of support in the priority document for the respective compounds which are respectively the same as the compounds in RE Claims 16-24.

RE Claims 71-78 which depend from RE Claim 39 are supported by the support identified hereinbefore for RE Claim 39 in terms of the method; and by the identification of support in the priority document for the respective compounds which are respectively the same as the compounds in RE Claims 16-24.

Respectfully submitted,

HERBERT GOODMAN Rea. No. 17,081

Date: September 19, 2001